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Audible frequency vibration of puncture-access medical devices

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ABSTRACT

Ultrasonic vibration has been proven to help scalpels and puncture devices cut and cauterize, but creates a damaged tissue zone that may not be desirable. We have found that audible frequency vibration applied to a needle not only reduces puncture force more than ultrasonic vibration; it does not cause significant immediate tissue damage. Here we thus present a method for decreasing the force required to insert a puncture-access medical device and an analytical model for predicting performance of a hypodermic needle, which correlates well with tests and shows that needle insertion force is lowered not only by decreasing the outer diameter of the needle, but also by driving the device at its free state resonant (amplitude-maximizing) frequency. Finally, an in vivo histology study is conducted and suggests that audible frequency vibration results in the same degree of immediate local tissue damage as simple manually inserted needles, but that it causes significantly less immediate local tissue damage than ultrasonic vibration.

1. Introduction and background

Numerous procedures in nearly every field of medicine require the insertion of an access device into a tissue medium along an axial path. Hypodermic needles, laparoscopic trocars, and other similar devices require an axial force to be applied by the user in order to penetrate various tissue layers. This force is determined not only by the geometry of the device itself but also by the mechanical properties of the tissue medium that it penetrates. Due to the complexity and variability of the human body, a device will likely encounter many different types and configurations of tissue along its insertion path, and the insertion force may vary significantly. A potentially harmful situation arises when the device punctures a tissue layer and the resistance force decreases suddenly. A force imbalance is created and causes the device to accelerate further into the tissue until the user is able to react and decrease the force they are applying to the device. Acceleration is directly proportional to applied force; a puncture device requiring a greater insertion force will have a greater force applied to it at the moment of puncture, and will therefore accelerate to a greater degree. If this acceleration is high enough and the user's reaction time significant, the device may even advance too far and damage delicate organs. If the force required to insert puncture access devices can be decreased, it is likely that epidural anesthesia, needle biopsies, amniocentesis, and other medical puncture procedures will be easier to perform and that complication rates will decrease.

In order to better understand the physics of needle-like device insertion, an analytical model for the force required to insert a needle into a medium is proposed. This model asserts that the axial insertion force has two components: the force due to friction acting on the outer surface of the needle, and the "tip force" applied to the end of the needle by the compressed column of medium directly below it, such that

$$F_{\mathrm{Insertion}} = F_{\mathrm{Friction}} + F_{\mathrm{Tip}} \tag{1}$$

The frictional component of this force is due to sliding friction, defined as the product of the coefficient of dynamic friction and the normal force applied to the sliding surface. The normal force acting on the outer surface of the needle is applied by the region of medium that is compressed in the radial direction as the needle is inserted, similar to a pin press-fit into a hole. Slocum [1] gives the interface pressure for a pin pressed into a hole in a semi-infinite medium as

$$P_{\mathrm{Int}} = \Delta\left[D\left(\frac{1+\eta_0}{E_0} + \frac{1-\eta_1}{E_1}\right)\right]^{-1} \tag{2}$$

where Δ is the half the diametrical interference, in this case equal to the outer radius of the needle, D is the nominal interface diameter, in this case equal to the diameter of the needle, η_0 and η_1 are the Poisson's ratios of the pin and the medium, respectively, and E_0 and E_1 are the elastic moduli of the pin and the medium, respectively. It is reasonable here to assume that the needle deforms a negligible amount ($E_0 \gg E_1$), simplifying (2). The product of the interface pressure and the needle surface area in contact with the medium, A_C,

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yields the normal force applied to the outer surface of the needle as

$$F_{\text{Normal}} = A_C \cdot P_{\text{Int}} = 2\pi l R \cdot \frac{E_m}{2(1+\eta_0)} = \frac{\pi E_m l R}{1+\eta_0} \tag{3}$$

where E_m is the elastic modulus of the medium, l is the length of the needle that is inserted into the medium, and R is the outer radius of the needle. The force of friction is given as

$$F_{\text{Friction}} = F_{\text{Normal}} \cdot \mu_d = \frac{\pi E_m l R \mu_d}{1+\eta_0} \tag{4}$$

where μ_d is the coefficient of dynamic friction between the needle and the medium.

The "tip force" component of the insertion force is the force applied to the needle by the compressed column of medium directly below the needle tip. A challenge arises in determining how far the column elastically deforms before being cut or torn apart by the sharp edges of the needle tip. As the exact deformation is not needed to compare different concepts in this study, a deformation of $2R$ is assumed, where R is the outer radius of the needle. Using St. Venant's principle, it can be assumed that this local deformation only affects a region of the medium that is within three characteristic dimensions from the needle tip, or six times R [1]. Therefore, the column is modeled as a spring with original length $6R$ compressed by $2R$. To determine the column's stiffness, the maximum total needle area is used rather than the area of the annulus formed by the needle alone, since the needle is assumed to contain a stylet or a static column of fluid. A "cutting coefficient" B is introduced that accounts for the effect on tip force of the specific needle tip geometry. Possible values of B range from 0 to 1, such that the spring model represents the maximum value for tip force. The tip force is given as

$$F_{\text{Tip}} = \frac{\pi E_m R^2}{3} \cdot B \tag{5}$$

The total force required to insert the needle into the medium is given by combining (4) and (5) such that

$$F_{\text{Insertion}} = F_{\text{Friction}} + F_{\text{Tip}} = \frac{\pi E_m l R \mu_d}{1+\eta_0} + \frac{\pi E_m R^2}{3} \cdot B \tag{6}$$

This model is similar to others found in the literature. Kataoka et al. [2] present needle insertion force as the sum of the tip force and frictional force, and experimentally demonstrates that the friction force is linearly proportional to the needle's inserted length. Okamura et al. [3] demonstrate a positive correlation between needle diameter and insertion force, stating that a larger needle causes greater local tissue compression resulting in higher friction forces. Experimental results by Davis et al. [4] suggest that the force on the tip of a needle compressing tissue is linearly related to the full (not annular) cross sectional area of the needle tip.

It is important to note that this model assumes that the needle is a rigid member, as it does not compress or buckle, and that the model does not address possible lateral deflection. The needles used in this study were all significantly stiffer than the medium into which they were inserted. In addition, this model assumes steady state penetration during which discrete puncture events do not occur. As such, the tip force remains constant.

2. Concept

The concept proposed in this study is to drive a needle-like device to oscillate linearly along its longitudinal axis at audible frequencies. This concept is intended to lower the force required to insert a needle-like device by lowering both the frictional and tip forces. The device should oscillate at a frequency below a maximum value such that the insertion force is significantly lowered but there is not sufficient frictional heating for local residual tissue damage to occur. The concept is proposed to lower frictional forces in a similar way as random orbital sanders, which require significantly less force to move across a surface than a simple sanding block of the same mass. It is theorized that oscillation disrupts contact between the device and the medium, decreasing the effective frictional force.

This concept is also intended to reduce the tip force applied to the needle. As the device advances, its tip makes many high-force small-amplitude penetrations into the tissue directly in front of it. The user experiences the insertion force in addition to the average force delivered by the vibrating component of the device, which is tactilely zero since the device vibrates at a relatively high frequency. However, each time the device tip is driven forward, this "vibration driver force" combines with the insertion force applied by the user to create a higher force applied to the tissue. Therefore, less average force is required by the user to penetrate a given tissue medium. In fact, doctors employ a similar technique in current practice by which they manually apply short, controlled "bursts" of force to a needle-like device in order to pierce a layer of tissue without traveling too far [5]. In this way, vibrating the needle could allow the needle to punch its way through tissue in small increments.

3. Existing devices

The idea of applying vibration to medical instruments is highly prevalent in both patent literature and current medical practice. Ultrasonic cutting devices are common in many surgical specialties including laparoscopy and cosmetic surgery. Although ultrasonic instruments employ vibration to decrease cutting or insertion force, their function relies on frictional heating and cavitation to denature proteins and vaporize intracellular fluid [6]. Depending on the amplitude and frequency at which an ultrasonic device oscillates, the distance from the device tip at which cells are damaged or broken down can be significantly increased. In procedures such as needle injections where tissue damage is usually highly localized, ultrasonic vibration might significantly enlarge the region of tissue damage and cause more pain or harm to the patient. Unlike ultrasonic instruments, the devices proposed in this study rely exclusively on the application of force over a very small area to break through tissue layers, only injuring cells directly adjacent to the insertion path.

The use of vibration in medical treatment has other potential applications. Sonoporation is the tendency of holes in cell membranes to expand when excited to high frequencies, allowing larger molecules including therapeutic agents to enter the cells [7]. US patent 5,647,851 describes vibrating a needle to "confuse nerve endings" and decrease the pain felt by a patient during a procedure [8]. US patent publication 2003/0083619 A1 describes a drug delivery device and includes a dependent claim where a needle is "vibrated along its length to reduce the force required to drive the needle into the body" [9]. However, no information is given in support of this claim or on ideal vibration parameters.

4. Proof of concept: experimental methods

To test the analytical model and concept proposed above, three needle configurations were constructed. The "NN" configuration was a standard 3.81 cm long 16 gauge lancet-tip hypodermic needle (BD 305198). The "VN" configuration was a standard 3.81 cm long 16 gauge lancet-tip hypodermic needle that was driven to oscillate linearly along its long axis at 150 Hz. The needle was fixed to the dust cap of a Jameco 135812 5W voice coil speaker driven by a function generator and power amplifier. The vibration frequency was determined by driving the speaker at close to 0 Hz and increasing